

"Apparently no certain medication has been discovered to date which will cure piles nor are the specific causes known. They are known as hemorrhoids in medical terminology, and consist of swollen veins in the lower end of the large intestine, or anus, brought on by such causes as constipation, infection, overstraining, heredity, childbirth, tension, worry and diet.

"If they protrude, they are known as external as distinguished from internal hemorrhoids, and when dilated they are very painful. Very often they bleed. Temporary relief comes with the lessening of congestion. Sometimes, as with common colds, piles cure themselves.

"A controlled experiment was conducted at Bellevue Hospital by Dr. Max P. Cowett, a distinguished proctologist. He testified that twenty-eight patients, interspersed between hospital and clinic patients were treated with Elip tablets for a period of almost four months. An additional twenty were given placebos in the form of milk sugar tablets. The results were uncomplimentary to Elip. Several of those using the tablets grew worse, or complained of abdominal cramps, with increased bowel movements, and tenesmus, or bowel frustration. The experiment with some patients had to be discontinued. Several required either surgery or sclerosing. None of the patients on either the Elip or the placebo benefited during the treatment.

"Various newspaper and periodical advertisements were submitted in evidence as proof of the intent of the labels, although not as evidence of the labeling itself. Such evidence is competent. *Colgrove v. United States*, 9 Cir., 176 F. 2d 614, certiorari denied 338 U.S. 911; *Research Laboratories v. United States*, 167 F. 2d 410, certiorari denied 335 U.S. 843; *United States v. Vitamin Industries, Inc.*, D.C. Nebr., 130 F. Supp. 755.

"In newspaper advertising and throwaways, the claimant made claims for the tablets such as: 'Piles checked in 72 hours with tablets * * * in 72 hours the bleeding stopped * * * Elip brings sure relief from pile misery * * * the only internal pile remedy.'

"It is plain that the claimants entered into a campaign of 'bait advertising.' A product, manufactured as a laxative, without any changes by the promoters, is held out to the unsuspecting public as a remedy for another condition, piles. The recklessness of the claimants and their utter disregard of those whom they catered to is evidenced by their admission that the tablets could not aid anyone afflicted with bleeding piles. That the element of large profit was not absent from this enterprise is inferable. The tablets cost the claimants about one-tenth of a cent each and were sold by the claimants at \$2 per package of 12 tablets. It is fairly apparent that if the claimants had informed the purchasers that the product was nothing more than a laxative, they would have been obliged to compete with the large number of producers of that article and would not have interested the pile sufferers.

"A decree is directed for the relief demanded in the libel."

In accordance with the above opinion, judgment of condemnation was entered on 6-10-57, and the product was ordered destroyed.

5448. Multizyme. (F.D.C. No. 40552. S. No. 74-325 M.)

QUANTITY: 777 unlabeled 8-oz. btls. and 1,596 unlabeled 4-oz. btls. at Seattle, Wash., in possession of Enzymes Products Co., Inc.

SHIPPED: 2-8-57 and 2-13-57, from Anaheim, Calif., by Ward Erickson.

ACCOMPANYING LABELING: Loose labels designated as "Multizyme Formula W.E. 8 ["or 4"] fl. ozs.," leaflets designated as "The Revolutionary New Multizyme * * * Put your Health in Balance," and order cards designated as "Multizyme * * * Special Trial Offer."

RESULTS OF INVESTIGATION: The accompanying labeling of the article was printed locally for the consignee.

LIBELED: 8-12-57, W. Dist. Washington; amended libel 8-14-57.

CHARGE: 502(a)—the name "Multizyme," by which the drug was designated while held for sale, was misleading since it suggested the presence of multiple enzymes in the article as the valuable factor needed in a food supplement for human nutrition, whereas such was not the fact; and, in addition, the leaflets and order cards accompanying the article, while held for sale, contained false and misleading representations that the article would keep the bloodlines of the body clean and so protect one from high blood pressure, and that it would correct the suffering caused by the lack of balance of forces within the body cells; 502(b) (1) and (2)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e) (2)—when shipped, the article failed to bear a label containing the common or usual name of each active ingredient contained therein; and 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: 12-23-57. Consent—claimed by Lee V. Schneider, Seattle, Wash., and relabeled.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM
OFFICIAL OR OWN STANDARDS***

5449. Posterior pituitary injection. (F.D.C. No. 40200. S. No. 54-805 M.)

QUANTITY: 99 1-cc. vials at Lynwood, Wash.

SHIPPED: 3-19-57, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: "1 cc Amp. Pituitary Extract 10 U. S. P. Units (Obstetrical)
* * * Control No. 020477 * * * Vitamix Corporation Philadelphia, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was less than 0.062 U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 5-16-57, W. Dist. Wash.

CHARGE: 501(b)—the strength of the article, when shipped, differed from the standard for "Posterior Pituitary Injection" set forth in the United States Pharmacopeia; and 502(a)—the label statement "1 cc Amp. Pituitary Extract 10 U. S. P. Units" was false and misleading as applied to a product, the potency of which is less than 10 U. S. P. posterior pituitary units per cubic centimeter.

DISPOSITION: 7-23-57. Default—destruction.

5450. Progesterone-estrogen. (F.D.C. No. 40367. S. No. 65-086 M.)

QUANTITY: 31 vials in a carton at Columbus, Ohio.

SHIPPED: 4-12-57, from Sarasota, Fla., by Stilco Laboratories.

LABEL IN PART: (Ctn.) "Stilco Laboratories * * * Sarasota, Florida,
35 x 10 cc — Control #956 — Progesterone-Estrogen In Sesame Oil — Intra-
muscular — Per CC Progesterone USP 25 MGM — Estrogens (95-98%
Estrone) 25,000 I. U."

RESULTS OF INVESTIGATION: Analysis showed that the article was an oil solution containing 21.6 percent of the declared amount of estrogens.

LIBELED: 7-2-57, S. Dist. Ohio.

*See also Nos. 5443, 5446.